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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO.       |
|---|-------------|----------------------|---------------------|------------------------|
| 09/847,102  | 05/01/2001  | Dennis A. Carson     | 220002062900        | 5759                   |
| 7590  | 03/02/2004  |                      |                     | EXAMINER<br>YU, MISOOK |
| Kevin L. Bastian, Esq.<br>Townsend and Townsend Crew LLP<br>Two Embarcadero Center, Eitht Floor<br>San Francisco, CA 94111-3834 |             |                      | ART UNIT<br>1642    | PAPER NUMBER           |

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/847,102             | CARSON ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | MISOOK YU, Ph.D.       | 1642                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 December 2003.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-8, 16, 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-8, 16, 28, 29 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## DETAILED ACTION

### ***Election/Restrictions***

Claims 1, 4, and 16 are amended. Claims 28, and 29 are new.

Claims 1-8, 16, 27, and 28 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### ***Claim Rejections - 35 USC § 112***

The rejection of claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of the amendment.

The rejection of Claims under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **withdrawn** since the claims recite specific sequence.

Claim 5 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim is interpreted as drawn to antibody capable of inhibiting binding of a genus of Wnt ligand to frizzled 5 receptor. Applicant argues that Wnt-5A had been known in the art at the instant application was filed. This argument has been fully considered but found unpersuasive because applicant argues

a limitation not present in the claim. Amending the claim "a Wnt lignd" to "Wnt-5A" would obviate this rejection.

***Claim Rejections - 35 USC § 103***

Claims 1-8, 16, 22, remain rejected for reason of record and the new claims 28, and 29 are also rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Tanaka et al (IDS, #1711998, Proc. Natl. Acad. Sci. USA. vol. 95, pages 10164-9), He et al (IDS # 93, 1997, Science vol. 275, pages 1652-4), or Wang et al (IDS #184, 1996, J. Biol. Chem. vol. 271, pages 4468-76) in view of Campbell, A. (1986, Monoclonal antibody technology, chapter 1 only, Elsevier Science Publishers B.V., Netherlands.

The claims are interpreted as drawn to antibody by itself, or label attached, or cytotoxic agent attached, capable of binding to instant SEQ ID NO:68.

Applicant argues that Wang et al did not know the extracellular domain; He et al, or Tanaka et al did not disclose importance of the protein in cancer or cell proliferation; Campbell does not discloses how to use frizzled 5 protein to produce antibodies. These arguments have been fully considered but found unpersuasive because the claims are drawn to antibody per se. The intended use and/or preamble of the claims for a product is not given the patentable weight.

Based on the prosecution history, the discovery of the human frizzled 5 receptor comprising instant SEQ ID NO:68 and where the extracellular domain lies in said human frizzled 5 receptor are not discovered by the inventors of the instant application. As the sequence alignment provided in the previous Office action indicates, both He et al and Tanaka et al are dealing with the same protein. Ex Part Gray (BdPatApp&Int, 10

USPQ2d 1922) has established that the prior art did not have to list the amino acid sequence in order to establish a protein is the same material. He et al established that N-terminal domain is important for signaling in vivo.

Campbell is presented here to show the current state of antibody technology and also to show that one in ordinary skill would be motivated to make antibody from a known protein sequence for reasons other than the intended purpose stated in the instant claim.

The Board of Patent Appeals and Interferences has taken the position that once an antigen has been isolated, the manufacture of antibodies against it is *prima facie* obvious. See Ex parte Erlich 22 USPQ2d 1463 (BdPatApp&Int 1992).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne C Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.  
Examiner  
Art Unit 1642



LARRY R. HELMS, PH.D  
PRIMARY EXAMINER